

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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|-------------------------|---|------------------------------|
| BENTLEY A. HOLLANDER, | : | |
| | : | |
| Plaintiff, | : | CIVIL ACTION NO. 2:10-cv-492 |
| | : | |
| | : | |
| v. | : | |
| | : | |
| | : | |
| EUSA PHARMA (USA), INC. | : | |
| | : | |
| Defendant. | : | |

ANSWER TO COMPLAINT

Defendant EUSA Pharma (USA), Inc. (“EUSA”), through its attorneys, answers the complaint of Plaintiff Bentley A. Hollander (“Hollander”) as follows:

1. Defendant admits that the complaint in this action purports to state a claim for false patent marking.
2. Denied.
3. Defendant admits that Hollander seeks a fine. Defendant lacks sufficient knowledge and information to form a belief regarding the remaining allegations in this paragraph, and denies the allegations on that basis.
4. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.
5. Admitted.
6. Denied.
7. Defendant admits that it has its corporate offices in the Eastern District of Pennsylvania, it has conducted and conducts business in this judicial district and that it sells products in this judicial district. Defendant denies the remaining allegations in this paragraph.
8. Denied.

9. Admitted.
10. Admitted.
11. Admitted.
12. Admitted.
13. Admitted.
14. Denied.
15. Admitted.
16. Admitted.
17. Defendant admits that its package inserts for ProstaScint® used to include U.S. Patent Nos. 5,162,504, 4,741,900 and 4,671,958 and that U.S. Patent No. 5,162,504 has not expired. Defendant denies the remaining allegations in this paragraph.
18. Defendant admits that its website used to include reference to U.S. Patent Nos. 5,162,504, 4,741,900 and 4,671,958 and that U.S. Patent No. 5,162,504 has not expired. Defendant denies the remaining allegations in this paragraph.
19. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.
20. Defendant admits that its package inserts for ProstaScint® used to include U.S. Patent Nos. 5,162,504, 4,741,900 and 4,671,958 and that U.S. Patent No. 5,162,504 has not expired. Defendant denies the remaining allegations in this paragraph.
21. Defendant admits that it manufactured and sold ProstaScint® having package inserts that used to include U.S. Patent Nos. 5,162,504, 4,741,900 and 4,671,958 and that U.S. Patent No. 5,162,504 has not expired. Defendant admits that ProstaScint® was sold in the United States and in this judicial district. Defendant denies the remaining allegations in this paragraph.
22. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.
23. Denied.

24. Denied.

25. Denied.

26. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.

27. Defendant admits that its package inserts for ProstaScint® used to include U.S. Patent Nos. 5,162,504, 4,741,900 and 4,671,958 and that U.S. Patent No. 5,162,504 has not expired. Defendant denies the remaining allegations in this paragraph.

28. Denied as to Defendant. Defendant lacks sufficient knowledge and information to form a belief regarding the remaining allegations in this paragraph, and denies the allegations on that basis.

29. Denied as to Defendant. Defendant lacks sufficient knowledge and information to form a belief regarding the remaining allegations in this paragraph, and denies the allegations on that basis.

30. Defendant admits that ProstaScint® is covered by U.S. Patent No. 5,162,504, which has not expired, that no injury has occurred to any entity, and that no one has been discouraged or deterred from honest competition or innovation in competing products. Defendant denies the remaining allegations in this paragraph.

**COUNT I
THE '958 PATENT**

FALSE MARKING OF PROSTASCINT® BY CYTOGEN

31. Defendant incorporates its responses to the foregoing paragraphs as though fully set forth herein.

32. Admitted.

33. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.

34. Defendant admits that after June 9, 2004, any units of ProstaScint® marked with patents included both expired and unexpired patents.

35. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.

36. Denied.

37. Admitted.

38. Defendant admits that Cytogen was merged into Defendant. Defendant denies the remaining allegations in this paragraph.

39. Admitted.

40. Denied.

**COUNT II
THE '958 PATENT**

FALSE MARKING OF PROSTASCINT® BY EUSA

41. Defendant incorporates its responses to the foregoing paragraphs as though fully set forth herein.

42. Admitted.

43. Denied.

44. Defendant admits that after June 9, 2004, any units of ProstaScint® marked with patents included both expired and unexpired patents.

45. Denied.

46. Denied.

**COUNT III
THE '900 PATENT**

FALSE MARKING OF PROSTASCINT® BY CYTOGEN

47. Defendant incorporates its responses to the foregoing paragraphs as though fully set forth herein.

48. Admitted.

49. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.

50. Defendant admits that after June 9, 2004, any units of ProstaScint® marked with patents included both expired and unexpired patents.

51. Defendant lacks sufficient knowledge and information to form a belief regarding the allegations in this paragraph, and denies the allegations on that basis.

52. Denied.

53. Admitted.

54. Defendant admits that Cytogen was merged into Defendant. Defendant denies the remaining allegations in this paragraph.

55. Admitted.

56. Denied.

**COUNT IV
THE '900 PATENT**

FALSE MARKING OF PROSTASCINT® BY EUSA

57. Defendant incorporates its responses to the foregoing paragraphs as though fully set forth herein.

58. Admitted.

59. Denied.

60. Defendant admits that after June 9, 2004, any units of ProstaScint® marked with patents included both expired and unexpired patents.

61. Denied.

62. Denied.

PENALTY

63. Defendant admits that each package insert for ProstaScint® that includes a patent marking includes reference to U.S. Patent No. 5,162,504, which has not expired, that no injury has occurred to the sovereign interests of the United States of America, that no injury has occurred to the public interest, and that no one has been discouraged or deterred from honest

competition or innovation in competing products. Defendant denies the remaining allegations in this paragraph.

64. Defendant admits that each use in advertising for ProstaScint® that includes a patent marking includes reference to U.S. Patent No. 5,162,504, which has not expired, that no injury has occurred to the sovereign interests of the United States of America, that no injury has occurred to the public interest, and that no one has been discouraged or deterred from honest competition or innovation in competing products. Defendant denies the remaining allegations in this paragraph.

AFFIRMATIVE DEFENSES

Without altering the burden of proof, Defendant asserts the following defenses: estoppel, laches, waiver, acquiescence and statute of limitations, which are based upon an investigation that is not complete and prior to the results of any discovery from Hollander. Defendant's investigation of its defenses is continuing, and Defendant reserves the right to assert all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, and any other defense, at law or in equity, that may now exist or in the future may be available based upon discovery and further investigation in this action. In addition, Defendant asserts the following defenses:

1. Hollander fails to state a claim upon which relief can be granted.
2. Hollander lacks standing to assert claims of false marking under 35 U.S.C. § 292 and his claims should be dismissed pursuant to Fed. R. Civ. P. 12(b)(1).
3. 35 U.S.C. § 292, on its face and as applied, is unconstitutional as a violation of Article II of the United States Constitution.
4. Defendant does not falsely mark and has not falsely marked because ProstaScint® is marked with U.S. Patent No. 5,162,504, which has not expired. Further, U.S. Patent Nos. 4,671,958 and 4,741,900 covered ProstaScint® prior to their expiration.
5. Defendant does not falsely mark and has not falsely marked ProstaScint® for the purpose of deceiving the public in violation of 35 U.S.C. § 292.

6. Every ProstaScint® article marked with U.S. Patent Nos. 4,671,958 and 4,741,900 is also marked with a patent that has not expired, U.S. Patent No. 5,162,504, and therefore is not an unpatented article as required by 35 U.S.C. § 292.

7. No one in the public can be intentionally and/or mistakenly deceived into believing that an article is patented, when it is covered by and marked with a valid, enforceable, unexpired patent, because it is in fact patented. There is no deception.

8. Every ProstaScint® article marked with U.S. Patent Nos. 4,671,958 and 4,741,900 is also marked with a patent that has not expired, U.S. Patent No. 5,162,504, and therefore there is no intent to deceive as required by 35 U.S.C. § 292.

9. Every ProstaScint® article marked with U.S. Patent Nos. 4,671,958 and 4,741,900 is also marked with a patent that has not expired, U.S. Patent No. 5,162,504, and therefore there are no damages.

10. There is no harm or damage whatsoever due the regulatory restrictions, which require approval by the FDA for sale of a biologic such as ProstaScint®.

11. ProstaScint® is sold into a sophisticated market to sophisticated professionals, including physicians and pharmacists, and, as such, the public is not implicated as required by 35 U.S.C. § 292.

12. ProstaScint® is sold into a sophisticated market to sophisticated professionals, including physicians and pharmacists, that are not deceived into thinking an article marked with an expired patent can be copied when it is also marked with a patent that has not expired. There is no harm or damage.

13. The relief requested by Hollander exceeds what is permissible under the law.

PRAYER FOR RELIEF

Defendant respectfully requests that the Court enter judgment against Hollander and award Defendant the following relief:

- a. That the Court enter judgment in favor of Defendant and against Hollander;

- b. That the Court award Hollander nothing by its Complaint;
- c. That the Court declare that Defendant has not falsely marked any products in violation of 35 U.S.C. § 292;
- d. That the Court declare that this is an exceptional case and award Defendant its reasonable costs, expenses, and attorneys' fees in this action; and
- e. That Defendant be awarded any further relief that is just and proper.

Respectfully submitted,

September 10, 2010

S/W. Jackson Matney, Jr.

John V. Gorman (Pa. I.D. No. 80631)
Diana P. Cortes (Pa. I.D. No. 204274)
Morgan, Lewis & Bockius LLP
1701 Market St.
Philadelphia, PA 19103-2921
P. 215-963-5000
F. 215-963-5001

Admitted pro hac vice

W. Jackson Matney, Jr.
Robert Smyth
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

*Counsel for Defendant,
EUSA Pharma (USA), Inc.*

CERTIFICATE OF SERVICE

I, W. Jackson Matney, Jr., hereby certify that a true and correct copy of DEFENDANT'S ANSWER was served this 10th day of September, 2010 upon the following via the Court's electronic filing system:

Jacob C. Cohn
Ilan Rosenberg
Attorneys for Plaintiff
Cozen O'Connor
1900 Market Street
Philadelphia, PA 19103

S /W. Jackson Matney, Jr.